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The Effect of Biofeedback on Intimate Partner Violence: Study Protocol for a Randomized Controlled Trial

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ABSTRACT

***Background**: Studies on cognitive behavioral therapy (CBT) for intimate partner violence (IPV) offenders show small to no effects on recidivism. IPV-offenders may not fully benefit from CBT due to insufficient transfer and generalization from therapy to real-life situations. During CBT, patients are taught to detect bodily signals indicative of arousal. A possible reason that the transfer is insufficient might be that the arousal-provoking stimuli in therapy do not match the real-world provoking stimuli, and thus patients do not learn to sufficiently detect bodily signals preceding arousal in real-life. Recent research has shown that IPV-offenders differ in their psychophysiological reactivity depending on their main diagnosis. This might also have implications for learning transfer. We presume that IPV perpetrators cannot fully profit from CBT interventions in which self-control is taught from cognitive techniques instead of increasing physical awareness through biofeedback. In the present study we first want to test the hypothesis that biofeedback will increase awareness of bodily signals indicative of arousal. Second, we expect that the use of biofeedback will have beneficial effects on transfer to real-life situations resulting in a decrease of IPV. For this purpose, we developed a smartphone application, Good Reaction Is Prevention (GRIP), that when used in conjunction with a heart rate monitor measures heart rate variability and notifies users when a personal stress threshold is surpassed.*

***Methods/design**: The study takes place in an outpatient forensic treatment center. In a randomized controlled trial (N = 40) we compare a 9-week CBT-based program aimed at developing motivation and self-control where IPV offenders will be treated either with or without biofeedback. The primary outcome is change in frequency of IPV from pretest to posttest. Secondary outcomes are weekly self-report questionnaires on bodily sensations of anger and change in resting HRV-values between pre and post intervention.*

***Discussion**: To our knowledge, this is the first study to test the effects of a biofeedback application on IPV. This study will test a new intervention strategy which is expected to increase treatment effects by focusing on bodily awareness instead of cognitive processes.*

***Trial registration**: This study was registered with CCMO via ToetsingOnline.nl (Identifier NL69507.018.19).*

Keywords

Intimate partner violence, IPV, Goede Reactie Is Preventie, Biofeedback, Heart rate variability, HRV, e-health, Forensic outpatients, Randomized controlled trial.

Administrative information

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Name and contact information for the trial sponsor {5b}	**Kwaliteit Forensische Zorg** (KFZ) Tel: +31 (0)30 2910010 e-mail: info@kfz.nl **Stichting Koningsheide** Tel: 0570-604455 e-mail: stichtingkoningsheide@transfore.nl
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Background {6a} {6b}

Intimate partner violence (IPV) refers to the usage of physical, psychological or sexual violence from one partner to another within a current or past romantic relationship. A systematic review of 141 studies performed in 81 countries showed that 30% of all women of 15 years and older have been a victim of IPV at least once in their lifetime [1]. IPV has several major negative consequences, for victims as well as for society. IPV victimization has been associated with physical and psychological problems, such as depression, Posttraumatic Stress Disorder (PTSD) and suicidality [2–4]. Worldwide, societies bear an estimated cost of 4,423 billion dollars for consequences such as victim shelter, psychological treatment, medical care, legal procedures, as well as diminished societal participation of victims [5].

Current treatment of IPV

Considering these consequences of IPV, reducing its prevalence is of paramount importance. One approach that aims to combat IPV is to refer offenders to outpatient forensic mental health treatment because IPV-offenders often struggle with a variety of psychological problems, such as mental health disorders, relationship problems, substance abuse, and difficulties with stress management [6]. In Europe, Cognitive Behavioral Therapy (CBT) is the most commonly provided treatment modality [7,8]. While there is some evidence that CBT is marginally more effective than other forms of IPV treatments, its overall effect size remains small [9,10]. This is both a problematic and a puzzling outcome, considering that CBT has been proven effective for anger management and reducing aggressive behavior in general [11]. This raises the question why CBT insufficiently reduces IPV and how its transfer effects can be improved.

There are several reasons why IPV-offenders might not benefit from CBT as much as others. First, a key CBT-element is to teach self-control over behavior [12] this becomes problematic as IPV offenders have been found to have lower levels of self –control [13–15]. Second, IPV offenders are under constant threat to run into their aggression provoking partner. Third, the physiological reactivity of IPV offenders depends on their diagnosis and ability to empathize (cognitively and affectively) with others [16–18]. IPV offenders with borderline personality disorder (BPD) showed longer periods of anger compared to offenders with antisocial personality disorder (ASPD) and controls [17]. Moreover, while labeling affect, IPV offenders with BPD showed increased ANS reactivity as opposed to IPV offenders with primary psychopathy [18]. This differential reactivity will likely also have an effect on learning transfer to real-life situations.

These findings suggest the need of a different treatment approach IPV offenders. It is important to teach IPV offenders to become aware which internal and external stimuli lead to aggressive behavior. As research indicates that an internal state of heightened autonomic arousal precedes IPV [19], acquiring the skill of self-control is dependent on being/becoming aware of changes in autonomic arousal. A rise in autonomic arousal is accompanied by bodily symptoms such as a rapid heart rate, trembling, and shortness of breath [20]. These symptoms provide recognizable cues as to the state of the autonomic nervous system (ANS); however, research indicates that IPV offenders' ability to accurately self-observe these symptoms is hampered by several factors. Firstly, the offender's ability of rational cognitive processing decreases when autonomic arousal increases, making it more difficult to self-observe and attenuate this tension [21,22]. Secondly, they experience these symptoms as ego dystonic and outside of their control [23,24]. Furthermore, social information processing becomes biased toward supporting the autonomic state, possibly contributing to escalation [25].

Using HRV as biomarker

To summarize, IPV offenders show differential ANS reactivity depending on the type of diagnosis. In addition, they have an increased risk for violence as their partner, and thus the provoking stimulus, is around for the larger part of the day. As IPV offenders have problems becoming aware of changes in ANS functioning due to cognitive and emphatic deficits, the effects of CBT might be augmented by finding an apt way to teach self-observation skills.

Adding continuous biofeedback on the level of autonomic arousal to CBT could potentially contribute to helping IPV offenders become more aware of (bodily symptoms of) changes in level of arousal in real-life.

One of the key psychophysiological indices of ANS functioning is Heart Rate Variability (HRV) parameters. The ANS regulates functions such as metabolism, temperature and heart rate through the sympathetic and parasympathetic nervous system [26]. The sympathetic nervous system (SNS; fight or flight) regulates behavioral activation, measurable through increased heart rate and sweat excretion. The parasympathetic (PNS) branch regulates behavioral de-activation or homeostasis, more popularly known as rest and digest [27,28]. When confronted with a stimulus or stressor, the body reacts with a complex interplay of higher and lower order brain processing, increased heart rate, hormone secretion, muscle tension, and increased breathing rate [29]. HRV parameters can be used as an index of the relative innervation of both branches, as they are among the first to be activated in response to a stressor [30].

Research has shown that using HRV as a biomarker can improve the ability of self-control [29,31,32], attention control, emotional regulation [33], and cognitive flexibility [34]. Moreover, some studies have demonstrated the potential positive effect of biofeedback on reducing anger and aggression in treatment [35,36]. Research in other fields shows that wearable technology can contribute to achieving health-related goals by increasing self-regulative abilities [37]. In addition, it improves feelings of empowerment, which in turn might improve commitment to attaining health-related goals [38].

There are indications from research that point toward the potential utility of HRV as a biomarker for reducing IPV. A recent study found that in the 20 minutes preceding aggressive behavior of inpatients, levels of heart rate and electro dermal activity rise [39]. A reduction in parasympathetic activity, measured as a decrease in HRV, has also been found to precede a rising level of tension [40]. Other studies found that a decrease in HRV is related to reactive aggression in general [41,42], that low-level violence IPV offenders show autonomic hyper reactivity [43], and that sympathetic nervous system reactivity is related to reactive relational aggression [44,45]. Intense negative emotional experiences, like anger, are also accompanied by a lowering of HRV and are predictive of violent behavior [46,47].

As described earlier, indications of differential psychophysiological regulation have been found in IPV offenders, which implies that they may have difficulties controlling their autonomic state [48]. Taken together, prior research suggests that using HRV-feedback in IPV treatment could help IPV-offenders to become aware of their increasing arousal levels, which could provide them with time to cool down and attain control over their behavior. However, the number of studies is scarce and in general they do not use strong experimental designs [49].

Objectives {7}

With this study we investigate the usability of a well-researched biomarker through contemporary wearable and carriable technology with the aim of augmenting the (small) effects of treatment with CBT in order to reduce IPV. Primarily, we expect that the use of biofeedback will have beneficial effects on transfer to real-life situations, resulting in a decrease of IPV from pretest to posttest Secondly, we hypothesized that biofeedback will increase awareness of bodily signals indicative of arousal. Exploratively, we aim to investigate the differences in HRV-values from pretest to posttest.

Method/design

Design {8}

The study is a Randomized Controlled Trial (RCT) with a pretest-posttest design comparing two conditions: 1) a Treatment As Usual (TAU)-condition (n = 20), and 2) a GRIP-condition (n = 20), in which patients receive TAU plus biofeedback using the Good Reaction is Prevention (GRIP) smartphone application and a wearable heart rate monitor (see Materials). Interventions are provided within a 9-week time period. For an overview of the study, including all measurements, see (Figure 1).

Setting {9}

'De Waag' is an outpatient forensic mental health care center (part of 'De Forensische Zorgspecialisten') with 11 treatment sites throughout The Netherlands. Patients are referred by a probation officer after court mandation or of their own volition by a general practitioner, because of having committed an offense or being at risk of committing an offense. Multidisciplinary IPV teams at four treatment sites, located in Amersfoort, Flevoland, Haarlem and Utrecht, will include patients for the study. Every team consists of at least one psychiatrist and a mix of (mental health) psychologists, psychotherapists, clinical psychologists and family therapists. We do not distinguish between education years or experience, wanting the study results to give a valid representation of everyday practice. All teams received one-hour training about the study, and a detailed study protocol with extensive instructions per session.

Patients {10}

All patients will be adult male IPV offenders that are referred to 'de Waag' by their general practitioner. During the intake procedure therapists check on the following inclusion criteria that pertain to the research hypothesis: 1) lack of self-control as a risk factor and treatment target, 2) being in a romantic relationship and living together or seeing each other at least three times a week, 3) being in possession of a smartphone with iOS 11.2.5 or higher, or Android 6.0 or higher. Exclusion criteria are: 1) medical or other reasons that preclude wearing a chest strap with heart rate sensor, 2) a restraining order that prevents contact with the romantic partner, 3) stalking as reason for referral, 4) any reason that supersedes TAU, such as the need for immediate care with regard to suicidality, psychosis or imminent danger for others.

Sample size {14}

Sample size calculations using G*Power [50] indicate that 40 subjects (20 in each condition) are needed for repeated measures ANOVA analyses between and within conditions, assuming an effect size of $d = 0.35$ (conforming to the most methodologically sound IPV treatment studies [51]) at a power level of .80, an alpha of .05, and assuming a repeated measures-correlation of. 72 on the CTS-2 (see Materials).

Recruitment {15} {18b} {11c} {26a}

All patients that are registered for IPV treatment at the Waag are screened for eligibility by their therapist at the intake. If eligible, they are asked to participate in this study and given detailed verbal and written information on the study procedures. Patients have one week to decide whether they want to participate in the study and subsequently provide both verbal and written informed consent. To promote participant retention, patients in the GRIP-condition will be given a reward of €35 for completion of the whole study, which is distributed weekly during the study. Patients in the TAU-condition do not receive monetary rewards.

Randomization {16abc}

Randomization will be performed after written consent of the patient by means of a randomization program on the internet (https://www.graphpad.com/quickcalcs/randomize2). The randomization provides a different list every time it is used because it depends on the date and time of usage. Only the researchers have access to the randomization list. The therapist will be informed by email by the research assistant about the condition their patient has been assigned to after the patient signed informed consent.

Interventions {6b} {11a} {30}

The TAU-condition will be compared to a GRIP-condition. Patients in the TAU-condition receive a standard IPV treatment protocol which all IPV offenders at the Waag receive. Herewith, we aim to compare the GRIP-condition to the TAU-condition.

Preceding the start of the study, a psychodiagnostics procedure and ROM-instruments the Forensic Ambulant Risk Evaluation (FARE) [52] and Forensic Symptoms Inventory – Revised (FSI-R) [53] are filled out for treatment purposes. The subject's partner is invited to provide additional information on the current situation and safety issues and to assess whether conjoint treatment is safe and attainable. The ROM-procedure is repeated every 3-4 months to monitor changes in relevant dynamic risk factors. The ROM-instruments are not investigated in the current study.

TAU-condition

The TAU intervention in this study is the *Safety for Partners* treatment protocol. This workbook is developed by de Waag and is based on CBT and Emotion Focused Therapy principles and meets the Dutch Guidelines for Familial/Domestic Violence. The treatment program is offered to the individual patient or, preferably, as couples' therapy. It is aimed at minimizing the chance of a new escalation or abuse within the relationship. The partner(s) learn to control aggression and to deal with risky situations. In total, patients work with the treatment protocol for a period of 9-weekly sessions of 45 minutes each. For an overview of the study period and measurements, see (Figure 1). The treatment protocol contains the following elements: motivational interviewing, psychoeducation, drafting and using a safety plan, and the time-out procedure. These are described in more detail in the next section.

At the start of the treatment, Motivational Interviewing techniques are being used aimed at enlarging commitment to treatment, as well as identifying any reasons that may prevent the client from being motivated. Together with the therapist, the patient (and, if applicable, their partner) fills out a cost/benefit balance worksheet to cognitively evaluate what treatment might offer them in relation to personal life goals (e.g. for benefits 'I'd like to experience more intimacy in my relationship' and for costs 'I don't want to put any more effort into my relationship'). This cost/benefit balance worksheet results in a motivation score. If the patient is already motivated for treatment, these chapters are addressed more briefly.

Patients will then receive psychoeducation on anger, aggression, and the causes and consequences of IPV. Psychoeducation is targeted at different forms of aggression in general – instrumental and reactive – and IPV specifically. Possible causes of aggression will be discussed. Lastly, the relationship between stress and aggression is addressed. All psychoeducation topics are followed by applying this knowledge to the patient's own situation.

After the subject has been educated on IPV, a safety plan is being made in which the acquired knowledge on IPV is integrated. The safety plan is aimed at preventing escalation by agreeing upon which escalation-provoking situations and behaviors can be avoided. Agreed-upon safety behaviors depend on 'what works' for the subject and range from listening to soothing music, to taking a walk or calling a friend.

The time-out procedure is an extension of the safety-plan and focuses specifically on the safety behavior of physically leaving a situation in which there is risk of IPV. The rationale is that staying in the partner's vicinity while agitated or angry may lead to a point of hard-to-avoid aggressive behavior. Physically leaving gives one the opportunity to cool off before continuing to interact. Both partners will be included in the intervention as much as possible to enable them to adequately perform the time-out procedure. During the therapy sessions, the partners decide upon concrete aspects of the time-out procedure, i.e., when to leave, how to leave (e.g., what to say to make clear you want to take a time out), and when to return. This provides a feeling of safety that forms the basis for the follow-up treatment modules that target relationship skills, intimacy, and sexuality. Patients fill in a questionnaire about pros and cons of working with the time out procedure.

GRIP-condition

Patients in the GRIP-condition follow the above described TAU-procedure and in addition, they receive supportive biofeedback for a period of five weeks. The aim is to help IPV offenders become

aware of bodily signals that pertain to changes in autonomic arousal, enabling them to take a time-out before their ability to observe and control their behavior becomes impaired. Patients will wear a chest strap with a heart rate monitor attached to it (Polar H7; see Materials) as often as possible and comfortable, for a minimum of three times a week for three hours, predominantly in high risk situations during time spend with their partner. Situations that harbor a heightened risk of IPV will be defined with the therapist before the start of the study period. The heart rate monitor will be connected to the smartphone application, Good Reaction Is Prevention - GRIP (see Materials).

The GRIP-app converts heart rate data to HRV and translates this into a more user friendly 'stress value'. When a preset individualized stress threshold is surpassed, GRIP alerts the patient of increasing arousal by pushing a sound notification to their smartphone. Patients can either indicate that everything is okay, or if not, choose from several in-app intervention options to reduce stress. While the app includes several games and exercises, patients in this study are instructed to choose the 'time-out' option.

During treatment sessions, therapists and patients will discuss the context of situations wherein the GRIP-app detects stress or anger. This pertains to the secondary study objective, to obtain an impression of the feasibility and practical as well as future implications of using GRIP-app. For a detailed description of the heart rate monitor and the smartphone application, see Materials {18a}.

After the study period, the patients continue with regular treatment for as long as needed. No physical or psychological harm is foreseen from participating in this study.

Criteria for discontinuing or modifying allocated interventions {11b}

One of the inclusion criteria for this study is that the partners should be living together or sees each other at least three times per week. If the relationship ends and the partners interact less than 3 times a week, high-risk situations for IPV are considered absent or minimal, therefore, the patient's contribution to the study ends. In addition, therapists are instructed to discontinue the protocol in cases where safety cannot be guaranteed and inform the researchers accordingly.

Materials {12} {18a}

For an overview of the measurements, see (Figure 1) and (Table 1). As the main goal of IPV therapy is to decrease the level of IPV, the primary outcome of this study is the difference in IPV from pretest to posttest. To measure whether the biofeedback leads to improved self-observation, the secondary outcome is weekly self-reported bodily signals of anger. To measure whether biofeedback influences HRV values, the change in HRV value from pretest to posttest will also be analyzed exploratively.

Primary outcome

Conflict Tactics Scale-2 (CTS-2)

The Conflict Tactics Scale-2 (CTS-2) [54] is a 78-item self-report questionnaire that assesses concrete acts and events of IPV of the patient and the patients partner in the previous year. Its scales are named Negotiation, Physical Aggression, Injury, Psychological Aggression, and Sexual Coercion. The instrument requests respondents to approximate the number of times an event occurred within a chosen time span. Items are scored on a 7-point scale that ranges from 0 (*this has never happened*) to 6 (*this has happened more than 20 times*).

There is extensive evidence that the factor structure is consistent with the theory used to develop the CTS, and evidence showing internal consistency and test-retest reliability, and convergent and construct validity [55]. Research has demonstrated high levels of consistency for each subscale (Cronbach's alpha > 0.74) [56]. To fit our research hypothesis, we chose an assessment period spanning eight weeks pre- and post-treatment and summing the frequency scores on the Psychological and Physical Aggression Scales. We removed items pertaining to a partner's behavior, leaving 39 items that focus only on the patient's own behavior.

Secondary outcomes

Anger Bodily Sensations Questionnaire (ABSQ)

The Anger Bodily Sensations Questionnaire (ABSQ) [57] is an 18-item self-report questionnaire for measuring bodily sensations related to anger in interpersonal situations. Every ABSQ item begins with 'When I get tense because of somebody,' and is followed by a specific physiological response, e.g. 'I notice that my heart starts beating faster'.

The respondent answers to what degree the physiological response is experienced during an anger-provoking social situation on a Liker scale with 1 = 'Not at all,' 2 = 'A little,' 3 = 'Somewhat,' 4 = 'Much,' and 5 = 'Very much'. The items of the ABSQ have moderate to good test-retest reliability, r (60) = .82. A three-factor structure with acceptable to high internal consistency has been identified; item-to-factor loadings are all significant and range from .57 to .86. The internal consistency is good with a Cronbach's alpha of .93. The ABSQ is administered weekly to measure whether the GRIP intervention leads to a larger improvement in self-observation than TAU.

Heart Rate Variability (HRV)

HRV will be measured for patients in both treatment conditions by performing a baseline pretreatment measurement and a posttreatment measurement. A protocol derived from literature on HR-measurement [58] will be followed, wherein patients sit still for 5 minutes wearing a heart rate monitor, in this case a Polar H7 is connected to GRIP-app. After 5 minutes the current HRV value will be written down. This procedure is performed at the start of the study period, and at the end.

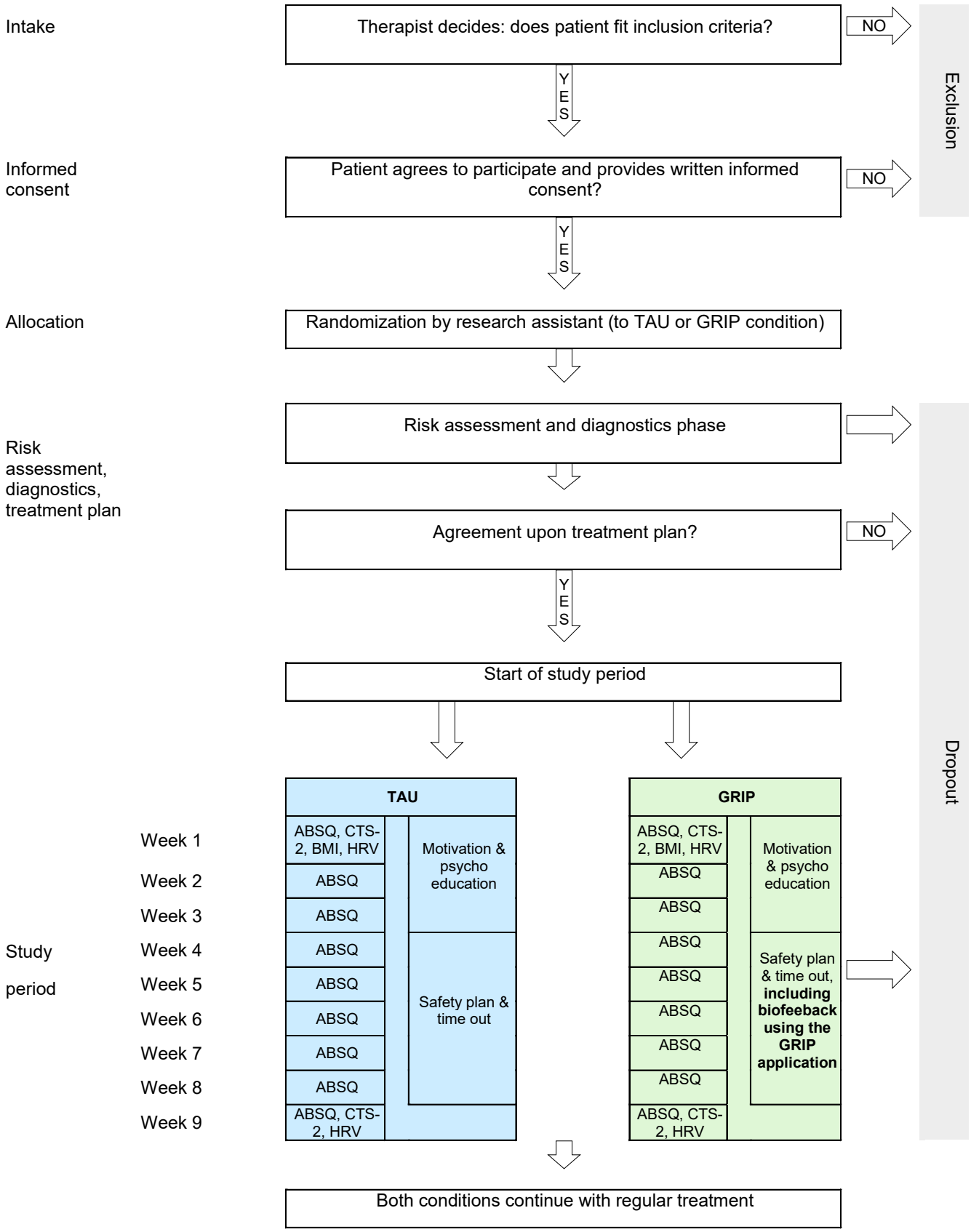

Figure 1: Overview of the study, including measurements

Note. TAU = Treatment As Usual; GRIP = Good Reaction is Prevention; ABSQ = Anger Bodily Symptoms Questionnaire; CTS-2 = Conflict Tactics Scale-2; BMI = Body Mass Index; HRV = Heart Rate Variability

Outcome	Measure	Hypothesis
Frequency of IPV	Conflict Tactics Scale-2 (CTS-2)	Patients in the GRIP-condition will show a larger decrease in CTS-2 scores from pre-test to posttest than patients in the TAU-condition
Awareness of bodily signals related to anger	Anger Bodily Symptoms Questionnaire (ABSQ)	Patients in the GRIP-condition will show a larger increase in ABSQ scores during the study period than patients in the TAU-condition
Resting HRV-values	Resting HRV-values	Exploratory: patients in the GRIP-condition will show a larger decrease in resting HRV-values from pretest to posttest than patients in the TAU-condition

Table 1: Primary and secondary outcome measures

Other materials and measurements

GRIP-application

The GRIP-application was developed by de Waag in collaboration with Mediamoose – with a grant from Kwaliteit Forensische Zorg (KFZ). The app is developed for people with problems controlling their anger and aggressive behavior. The purpose of GRIP-app is to support self-observation and commitment to practicing of self-controlling skills, by providing biofeedback on the state of the autonomic nervous system. The app works in conjunction with a heart rate monitor (see next paragraph) and displays the patient's heart rate per minute. In addition, the app converts the values of the heart rate monitor into HRV values using the 'time-domain pNN30 algorithm'. The application uses HRV and voice volume as indicators of the autonomic state by displaying a stress value on the users' smartphone. If the preset stress value and/or the voice volume threshold are surpassed, the application displays the notification "Is everything okay? *Stress/anger* has been detected". This enables the user to intervene before stress levels get so high that behavioral control becomes hard. Patients can indicate either false alarm, or time out. When they choose the time out option, a screen will appear with the following instructions: *'You chose to take a time-out. Breathe through your stomach and tell the other that you are taking a time-out. Then go away and do not respond to the other anymore. Do something that makes you calmer. You could call someone who can help you to calm down.'* To help them get calmer, patients can personalize the time-out screen by adding a picture of something/someone or add a phone number of someone they can contact.

Therapists have access to an online web-based dashboard to manage clients' accounts, settings and to view shared and saved data, but only when the patient agrees to sharing the data with his/her therapist. Data are collected when the stress exceeds a prior set threshold. The data include information on the date the threshold is exceeded, the stress values, an indication whether anger or stress has been detected, the duration of anger or stress, and the action (ignore, playing game, taking a time-out, etc.) the client chooses.

Polar H7

In this study, the heart rate is measured using the Polar H7 heart rate monitor. The heart rate monitor is fastened across the chest with an elastic strap. It detects the heart rhythm, the heart's electric signal, the accuracy and reliability of the electrocardiogram (ECG). Then, it provides a timing reference for the occurrence of heart beats and transmits this information to the GRIP-app. The app then calculates the number of heart beats per minute. The Polar H7 was chosen for this study as it measures heart rate as validly and reliably as professional ECG hardware with a correlation of $r = 0.996$[59].

Covariates

Studies have identified several covariates that are known to influence ANS functioning, such as age, sports, smoking, medication, and Body Mass Index (BMI) [60–63]. Therefore, the therapists note these possible covariates on a standardized form. To measure BMI, all participating sites are provided with scales and measuring rods. BMI is calculated using the formula: weight (kg) / length (meters)^2.

Data management {19} {27} {29}

Therapists fill out a standardized form during each session, which includes the abovementioned covariates, pretest and posttest HRV-value. Questionnaires are filled in on paper by the patients. All paper documents are stored inside a locked storage cabinet. The paper documents do not contain names, dates of birth, or other personally identifiable information. Data will be entered into SPSS anonymously by a researcher, and double checked by another researcher. SPSS files are stored in a secure Citrix environment. Only the researchers involved in this study have access to the data.

Statistical approach {20a} {20c}

All statistical analyses will be performed in SPSS. The result of the randomization will be analyzed by comparing the two conditions on baseline socio-demographic and clinical variables (i.e., age, education level, pretest HRV value, BMI, motivation, pretest-CTS-2 and ABSQ scores) using univariate analysis (*t*-tests for continuous measures and chi-square tests for categorical measures). If, despite the randomization, the groups differ significantly on one or more of these variables, these will be included in subsequent analyses as a covariate.

Differences between the TAU and the GRIP-condition in the dependent variables will be examined in a Repeated Measures (RM)-ANOVA within-between designs. The primary outcome is the combined frequency of physical and psychological aggression between pretest and posttest (CTS-2) as the within-subject variable, and the condition as between-subject variable. In all analyses, a p-value $<.05$ will be considered statistically significant.

Analysis of the secondary outcome, weekly self-report bodily sensations of anger (ABSQ), is similar in nature (i.e., RM-ANOVA). Thirdly, pretest and posttest HRV-values will be compared between the TAU and GRIP-condition using RM-ANOVA.

Several variables will be entered as covariates to test whether these have an influence on the investigated associations, for example

age, BMI, PTSD diagnosis, HRV, treatment motivation (score from the Safety for Partners workbook) and substance abuse.

To minimize missing data, therapists are instructed to check whether the patient completed all items of the questionnaires at all measurement points. If information is nevertheless still missing, missing data are checked with Missing Completely At Random (MCAR). Missing data will be imputed using the Full Information Maximum Likelihood (FIML, also known as "Raw Maximum Likelihood") procedure. FIML outperforms most common methods of handling missing data, including listwise, mean replacement, and pairwise data deletion [64].

Discussion

To our knowledge, this will be the first study to examine the added value of biofeedback on regular IPV treatment (GRIP). The hypotheses of the study are that – compared to TAU – patients in the GRIP-condition will report increased self-reported bodily signals of anger, decreased HRV values, and – consequently – show a decreased level of IPV.

Current CBT-based IPV interventions have suboptimal effects. Prior research suggests that offenders may not fully benefit from CBT-based treatment, because their awareness of arousal is low[19,20]. This can lead to increased arousal a level which at some point leads to uncontrollable behavior. Therefore, it is presumed that IPV offenders do not fully benefit from CBT interventions aimed at developing self-control.

To address this, we developed the GRIP-application, which provides biofeedback when HRV and/or voice volume thresholds are surpassed. Using the GRIP-application as an addition to standard CBT IPV-interventions may have a number of advantages. Firstly, the GRIP-app can increase the patient's awareness of arousal by pushing notifications to users when a personal stress threshold is surpassed. Secondly, the GRIP-application can be used in high-risk situations, such as being at home together with partner, instead of only during a therapy session. Moreover, if the patient agrees to this, the therapist has insight in situations wherein the HRV and voice volume surpassed the threshold indicating possible feelings of stress or anger. These situations can be addressed to gain more insight in possible (acute) risk factors for aggression. If the GRIP-app can support safety for both patient and his or her partner, intervention can be more focused to addressing structural (relational) problems. Furthermore, this study addresses recent developments in the forensic field, where self-awareness and self-direction, autonomy, and the employment of innovative technology are increasingly regarded as relevant.

However, there are some limitations to the GRIP study. Firstly, while we attempt to include a sample that is as representative for the IPV population as possible by not excluding certain disorders and disabilities, there were some exclusion criteria that had to be adhered to. Future research should investigate the effectiveness of the GRIP-app for those groups (e.g., women, patients who are unable to wear a chest strap). Secondly, wearing the chest strap can be uncomfortable with prolonged use. In the future, the use of heartrate-measuring watches with the GRIP-app should be investigated; however, their accuracy at this time is insufficient. Lastly, future studies should investigate the long-term effects of the GRIP-application by including follow up measurements.

Methodologically sound studies are scarce on the topics of IPV treatment and biofeedback. By investigating the effects of the standard IPV treatment protocol, this study adds to the body of knowledge of IPV treatment. In addition, this study will shed light on the effectiveness and the feasibility of using biofeedback and wearable's in forensic outpatients. If proven to be effective, the GRIP-app could be an addition to current IPV interventions in forensic outpatients. Reducing IPV is of great importance for victims as well as for society, and the GRIP-app could help reaching this goal.

Trial status

Ongoing. This study commenced recruitment in October 2019 and is currently recruiting. Protocol version: 1.

Additional files

Additional file 1: SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents.

Abbreviations

IPV: Intimate Partner Violence; PTSD: Posttraumatic Stress Disorder; CBT: Cognitive Behavioral Therapy; BPD: Borderline Personality Disorder; ASPD: Antisocial Personality Disorder; ANS: Autonomic Nervous System; SNS: Sympathetic Nervous System; PNS: Parasympathetic Nervous System; HRV: Heart Rate Variability; TAU: Treatment As Usual; GRIP: Good Reaction Is Prevention; FARE: Forensic Ambulant Risk Evaluation; FSI-R: Forensic Symptoms Inventory – Revised; CTS-2: Conflict Tactics Scale-2; ABSQ: Anger Bodily Signals Questionnaire; BMI: Body Mass Index; RM-ANOVA: Repeated Measures Analysis Of Variance; MCAR: Missing Completely At Random; FIML: Full Information Maximum Likelihood.

Declarations

Ethics approval and consent to participate {24}

All research procedures were approved by the Ethics Committee of the Academical Medical Center Amsterdam. This study was registered with CCMO via ToetsingOnline.nl (Identifier NL69507.018.19). All patients will be asked for their permission to report on the results of their data in publications.

Funding and dissemination {4} {22} {23} {25} {31a}

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The authors will write an English publication when all the data have been collected and analyzed. In addition, a Dutch report will be published at the website of Kwaliteit Forensische Zorg, one of the funding agencies.

Authors' contributions {31b}

UA conceived the study, led the proposal and protocol development. JvH was involved in the development of the GRIP-application and the study protocol. UA and JH wrote the first version of this study protocol article. PdL contributed to the design of the study and the study protocol. All authors read and approved the final manuscript.

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